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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,210

04/08/2004

Arthur E. Uber III

IN/03-003

8248

21140 7590 06/24/2009

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EXAMINER

MENDEZ, MANUEL A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

06/24/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/821,210	<b>Applicant(s)</b> UBER ET AL.	
	<b>Examiner</b> Manuel A. Mendez	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-30, 33, 50, 52-67, 69, 71, 72 and 74-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-15, 16-24, 25-30, 33, 50, 52-67, 69, 71-72, and 74-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-7 and 10-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Reilly** et al. (US 6,767,319; hereafter Reilly) in view of [**Winkler** (US 6,238,374) or **Cornacchia** et al. (US 5,472,403; hereafter Cornacchia)], in further view of **Polaschegg** (US 4,966,579), in further view of **Wojcicki** et al. (US 5,190,522; hereafter Wojcicki), and finally, in further view of **Sassano** (US 4,747,826).

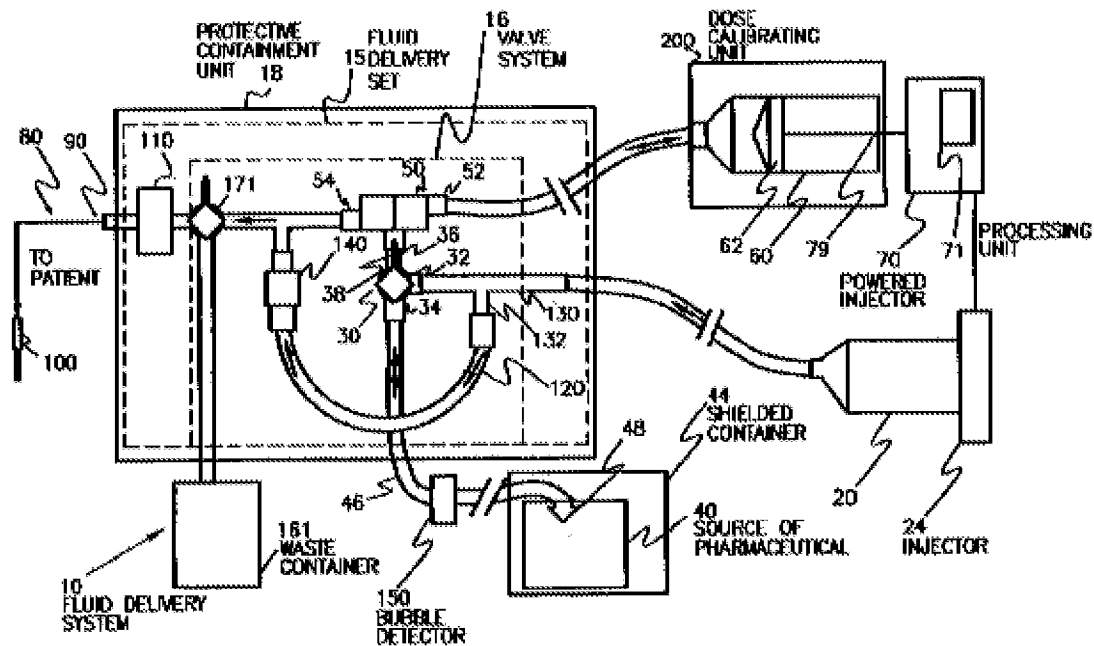
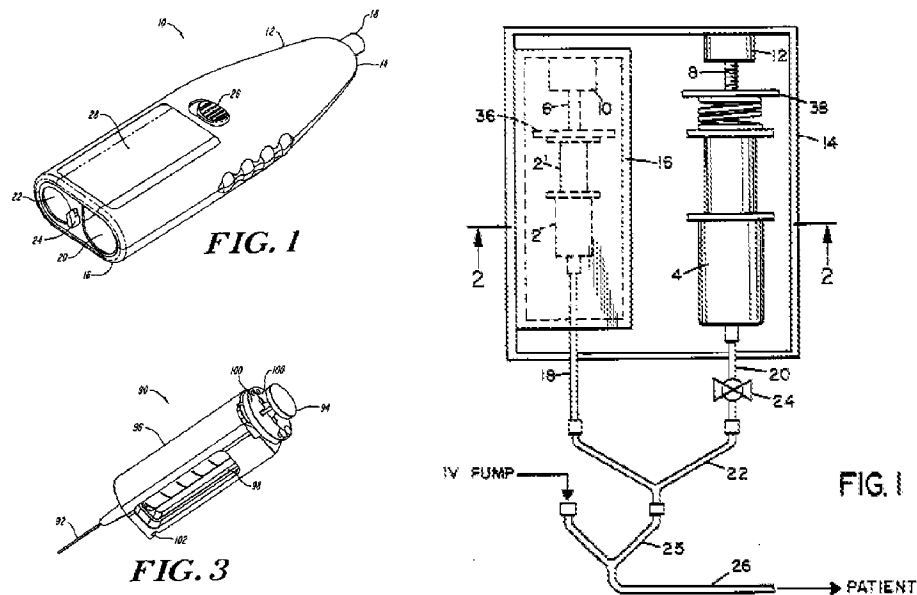


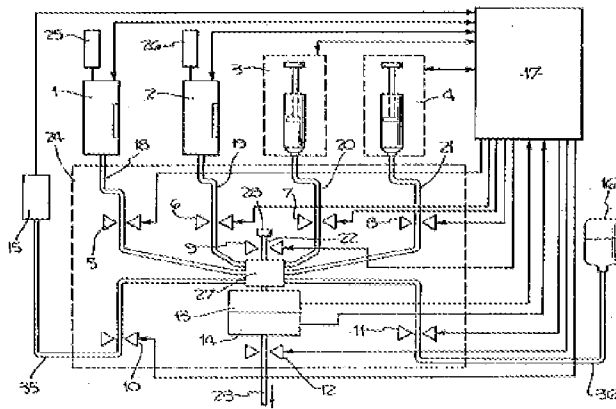
FIG. 1A

In figure 1A above, the Reilly patent shows:

- a container enclosing a hazardous pharmaceutical (shielded container (44);
- a first pump to deliver a hazardous pharmaceutical to a patient;
- a fluid path operably connected to the first pump, the container, and the patient; and
- a hazardous material containment suitable to confine the hazardous pharmaceutical during connection of the hazardous pharmaceutical container to the fluid path, and
- a waste container.



In order to further demonstrate the conventionality of hazardous material containment, the Winkler and Cornacchia patents are included in this rejection. In the figures above, both patents show the containment of reservoirs and infusion systems in order to protect medical personnel from contact with hazardous materials. Importantly, figure 1 of the Cornacchia patent also shows the use of multiple pumps and the use of non-hazardous fluid to flush and dilute the medication.



Concerning the use of more than two pumps in an infusion system, the Polaschegg patent shows in the figure above, a system for injecting a patient having a container, four infusion pumps, and a fluid path operably connected to the pumps, the container, and a patient.

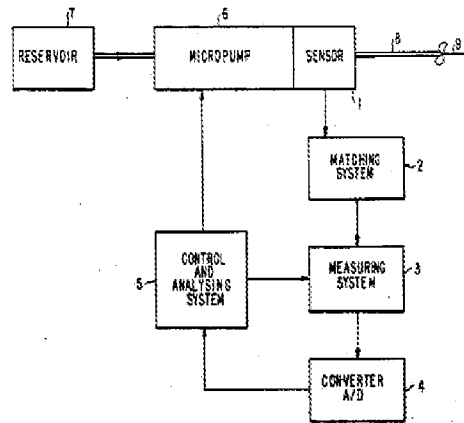
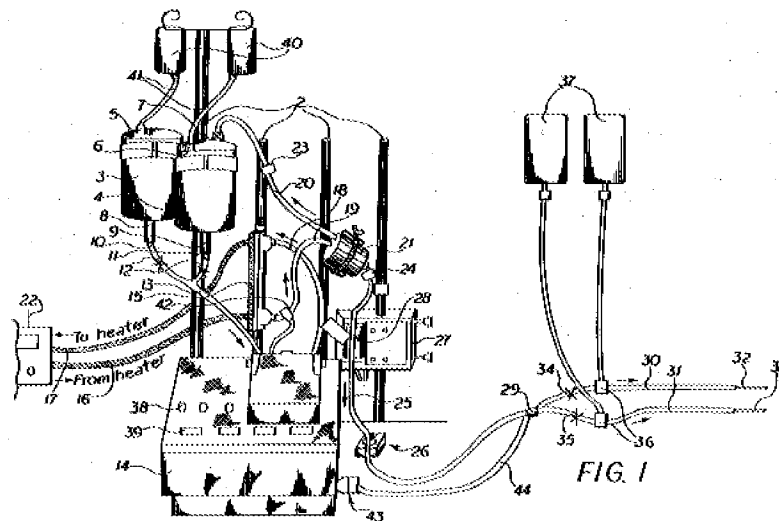


FIG. 1

Additionally, Wojcicki shows in figure 1, a control system to manage infusion based on value inputs of sensors measuring physiological conditions in the body.



Finally, the Sassano patent shows in figure 1, an infusion system designed with a heating/cooling unit used to heat and cool the fluid stored in the reservoir. The abstract of this patent summarizes this invention as:

The subject invention relates to a novel system for rapid, venous infusion of a physiologic fluid, such as blood, into a patient, comprising in combination a reservoir for the physiologic fluid having an inlet port for receiving the physiologic fluid and an outlet port for dispensing the physiologic fluid, an infusion pump to propel the physiologic fluid through the system, a heating/cooling unit to control the temperature of the physiologic fluid, a sensor to monitor the pressure of the physiologic fluid, one or more cannula for infusing the physiologic fluid into the venous system of the patient, and flexible conduits connecting the components of the system to the physiologic fluid to and from each of the components of the system.

Based on the comments and observations of the evidence presented above, for a person of ordinary skill in the art, modifying the infusion system disclosed by the Reilly patent with (1) hazardous material containment for fluid reservoirs and pumps, as taught by Winkler and Cornacchia, (2) additional pumps and reservoirs, as taught by the

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Polaschegg patent, (3) a control system with sensors to monitor physiological conditions to control infusion, as taught by Wojcicki, and finally, (4) with the capability to cool and heat the fluids stored in the reservoirs prior to infusion, as taught by Sassano, would have been considered obvious in view of the conventionality of this particular enhancements, and moreover, because (1) hazardous material containment prevents injuries of medical personnel, (2) additional pumps and reservoirs expands the infusion capabilities of the infusion system, (3) a control system enhances the beneficial response to drug infusion, and (4) the cooling or heating of medicaments prior to infusion prevents adverse reactions or shocks.

### ***Conclusion***

In view of the fact that the examiner did not address all the claims in the previous action and in order to provide applicant with the opportunity to comment on the merits of the newly presented references, this office action is not a final office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez  
Primary Examiner  
Art Unit 3763

MM